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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/509,604	09/27/2004	Peter Haynes Hutson	T1571P	2724

210 7590 04/03/2007

MERCK AND CO., INC
P O BOX 2000
RAHWAY, NJ 07065-0907

EXAMINER	
RAMACHANDRAN, UMAMAHESWARI	
ART UNIT	PAPER NUMBER
1617	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	04/03/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/509,604	HUTSON, PETER HAYNES	
	Examiner	Art Unit	
	Umamaheswari Ramachandran	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE ____ MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 January 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *19-25* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *19-25* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The examiner notes the receipt of the amendments and remarks received in the office on 1/26/2007 adding new claims 19-25. Claims 1-18 have been canceled. Claims 19-25 are pending.

The rejection of claims 12-18 under 35 U.S.C 112 first paragraph is withdrawn due to the cancellation of claims 1-18. Applicant's arguments filed 1/26/2007 regarding 35 U.S.C 103 rejection of claims 5-11 have been fully considered but they are not persuasive. In view of applicants' amendments and addition of new claims a modified 35 U.S.C 103(a) rejection is now made.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 19-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Curtis et al (GB 2306471) in view of in view of Baldessarini et al (WO 02/072029, effective filing date 3/12/2001) and further in view of Merck Manual.

Curtis et al. teaches that methane sulfonate salt of benzofuran derivative (as in claim 1) as an extremely potent antagonist of the human dopamine D_4 receptor (see Abstract) and is useful in the treatment and/or prevention of psychotic disorders such as schizophrenia (p1 lines 8-9). The reference does not teach the use of the compound in the treatment of ADHD.

Baldessarini et al. teaches a method of administering a dopamine D_4 receptor antagonist to a mammal to inhibit motor hyperactivity exhibiting the symptoms of ADHD (see Abstract, p1 para 003). The reference teaches that the dopamine D_4 receptor antagonist can be administered orally (p3, para 0029). The reference also relates to the treatments and therapies for attentional dysfunction associated with ADHD (p1 para 003). The reference teaches the administration of dopamine D_4 receptor antagonist to mammals including human (p1, para 0012) and that broadly covers a male, and a male aged 5-18 years.

As per Merck manual (Beers et al., Merck Manual, 17th ed. 1999, p 2255-58) it is estimated that ADHD affects 5-10% of school-aged children and is diagnosed 10 times more often in boys than in girls and many features of ADHD (p 2256 lines 1-12) are often noticed invariably before age 7, but they may not interfere significantly with academic performance and social functioning until the middle school years. Children with primary ADD often are not diagnosed until or after adolescence. Hence it is obvious for one of ordinary skill in the art to provide a method of treatment for male patients aged 5-18 years.

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to combine Curtis's and Baldessarini's teachings to use the benzofuran derivative, a dopamine D_4 receptor antagonist in a method of treating ADHD.

The motivation to do so is provided by Curtis et al. The reference teaches that the benzofuran derivatives are extremely potent antagonists of the human dopamine D_4

receptor subtype and has a selective affinity for the dopamine D_4 receptor subtype over the other subtypes, in particular the D_2 subtype and therefore be expected to manifest fewer side-effects than those associated with other drugs (p2 lines 10-19). In addition, the methane sulfonate salts possess advantageous qualities in terms of their improved aqueous solubility relative to the corresponding base and, as such provide for greater ease of formulation and display enhanced pharmacokinetic properties, including oral absorption (see Abstract).

Response to Remarks

Applicants' argue that Curtis et al. in view of Baldessarini et al. and further in view of Merck manual do not provide a motivation to employ the compound of formula I in claim 19 (new) for the treatment of attention-deficit/hyperactivity disorder. Curtis et al. clearly teaches that the compound of formula I is a dopamine D4 antagonist and Baldessarini et al. teaches a method of administering a dopamine D_4 receptor antagonist to a mammal to inhibit motor hyperactivity exhibiting the symptoms of ADHD. The reference also relates to the treatments and therapies for attentional dysfunction associated with ADHD. It would have been obvious to one of ordinary skill in the art at the time of the invention to administer a compound of formula I in a method of treatment attention-deficit/hyperactivity disorder because Curtis teaches the compound of formula I as dopamine D4 antagonist and Baldessarini et al. teaches dopamine D4 antagonists in the treatment of attention-deficit hyperactivity disorder.

Applicants' argue that Baldessarini et al. teaches the compounds (dopamine D4 antagonist) should be administered intramuscularly, intravenously or subcutaneously

(claim 5 of Baldessarini et al). The examiner would like to point out that Baldessarini et al. teaches that the dopamine D_4 receptor antagonist can be administered orally (p3, para 0029).

Applicants' claim that Baldessarini et al. (WO 02/072029) is published on September 19 2002 and is not effective as a reference under 35 U.S.C. 103 (a). The international filing date for PCT/US02/07651 is 12 Mar 2002 and the filing date of provisional U.S application 60/275,198 is 12 Mar 2001 and hence the effective filing date of this document is 12 Mar 2001. Hence the reference Baldessarini et al. (WO 02/072029) qualifies as a prior art as the effective priority date of the instant application under U.S.C 119 is Mar 26 2002 (filing date of GB 0207139.7).

Conclusion

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Umamaheswari Ramachandran whose telephone number is 571-272-9926. The examiner can normally be reached on M-F 8:30 AM - 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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SREENI
SUPERVISORY PATENT EXAMINER